REMARKS

Claims 1 and 22 have been amended to recite that the vehicle is configured to release the bioactive material when an implantable medical device onto which the coating is deposited is implanted. Near-verbatim support can be found in the specification at page 2, third paragraph of the specification. Claim 23 is newly added. Support can be found in the specification at page 2, third paragraph and at page 4, lines 10-14.

No new matter is added. Favorable reconsideration is respectfully requested.

Rejection of Claims 1-9 under 35 USC §103(a) Over Ding (U.S. Patent No. 7,294,329) in View of Hsu et al. (U.S. Patent No. 6,340,465) and the Kollidon VA 64 Technical Information ("Kollidon Reference"); Rejection of Claims 1-8 under 35 USC §103(a) Over Ding, in View of Hsu et al. and the Kollidon Reference, and Further in View of Sass (U.S. Patent No. 6,383,215):

Because these two rejections are very closely related, Applicants will argue them together.

These rejections are respectfully traversed on several grounds. First, the rejections are traversed because there is no motivation to combine Ding and Hsu et al. Because there is no motivation to combine the reference, the Office has not established a *prima facie* case of obviousness with respect to the claims. Specifically, the Office takes the position, in the first full paragraph of page 4 of the Final Office Action, that because "the implantation of a device would be facilitated by it having a lubricious outer surface (*e.g.*, easier and faster implantation)," it makes sense to combine Ding with Hsu et al. This reasoning, however, is fatally flawed because Ding is directed to coatings intended for use with drug-eluting cardiac stents, where lubricity (*i.e.*, slipperiness) is counter-indicated. See, for example, the abstract of Ding, as well as Ding at col. 2, lines 43-53. Note that Ding is completely silent with regard to any benefit to be had in increasing the lubricity of the coating described therein. Applicants submit that there is no benefit whatsoever (and in fact there is a very real danger) in increasing the lubricity of either the inner or outer surface of a stent.

A cardiac stent is deployed on the end of a balloon catheter. The collapsed stent is carried to the point of deployment on the surface of the deflated balloon catheter. The balloon catheter is

then inflated to expand and lock the stent into its open position and seat it within the lumen of an cardiac artery. The outer surface area of the collapsed stent is quite small compared to the surface area of the balloon catheter on which it is carried. (See, for example, http://www.youtube.com/watch?v=9FPapBbbS4o, which is short animated clip showing the deployment of a cardiac stent.) Because the vast majority of friction in positioning the catheter is due to the catheter itself (which is not implanted into the body), a lubricious coating on the outer surface of the stent will have little or no impact on the push force required to thread the catheter into place. Further still, stents are intentionally designed to stay in place once deployed. Slippage of the stent once deployed could have catastrophic (*i.e.*, fatal) results. Thus, making the outer surface of a stent lubricious is **not** advantageous as asserted by the Office at page 4 of the Final Office Action because it could cause the stent to migrate within the blood vessel after deployment. A slippery stent is definitely a disadvantage.

Likewise, a stent having a lubricious inner surface is a also distinct disadvantage because the stent might then slip along the length of the balloon catheter prior to or during deployment. Worse still, the stent might slip off the end of the balloon catheter prior to deployment. This would be truly catastrophic because the collapsed stent would then be loose within the blood vessel. Retrieving it without causing further harm to the patient would be very difficult.

Applicants further traverse this rejection because even if Ding and Hsu et al. are combined in the fashion suggested by the Office, polyvinylpyrrolidone-vinyl acetate copolymers (PVP/PA) are hydrophilic polymers—they are not lubricious and therefore will not function in the manner asserted by Office. In short, because PVP/PA is hydrophilic, it will not impart lubricity to a device onto which it is coated. See for Example, Exhibit A, attached hereto and incorporated herein. Exhibit A is product literature from International Specialty Products for PVP/VA copolymers. Exhibit A specifically indicates that films of PVP/VA films are characterized by "**adhesion**, luster, hardness, and **water rewettability**." A "wettable" surface is synonymous with a "hydrophilic" surface.

Applicants explicitly and strenuously traverse this rejection in light of the Office's statement that "Hsu et al... teach the inclusion of a PVA/VA copolymer in the coating **to enhance the lubricity**" of the coating. See page 4, second paragraph of the Final Office Action.

This simply is not the case. The passage cited by the Office in support of this contention, Hsu et al., column 3, lines 55-60 (emphasis added), says no such thing:

> Another variation of the present invention discloses coating compositions wherein **the biocompatible agent is a hydrophilic polymer**. In various embodiments, the hydrophilic polymer is selected from the group consisting of polyvinylpyrrolidone (PVP), PVP/vinyl acetate copolymer, and polyethylene oxide.

Nor does the passage at Hsu et al. column 9, lines 31-35, which prominently **does not** recite PVP/VA copoymers, but only the homopolymer of vinylpyrrolidone, and **unnamed** co-polymers of PVP. PVP/PA is mentioned by name only as a biocompatible agent that has the capability of **inhibiting** the lubricity of the crosslinked, unmodified coating. (See below for a further discussion.)

Claim 1 of Hsu et al. is utterly silent with respect to PVP/VA copoymers, so its citation in support of this rejection is inapposite.

Hsu et al. **do not** teach or even remotely suggest that the PVP/VA itself is lubricious. See column 3, lines 55-60 of Hsu et al., quoted above. The PVP/VA copolymer is recited as a "biocompatible agent," and not as the "polyfunctional polymer" required for lubricity. The PVP/VA does not contribute at all to the lubricity of the coating described by Hsu et al. In fact, Hsu et al. explicitly state that the "biocompatible agent" included in their coating, including PVP/VA (which is specifically identified, by name, as a "biocompatible agent") would be expected to inhibit or ruin entirely the lubricity of the unmodified coating. See Hsu et al. at column 5, lines 49-56:

> These additional functionalities can be imparted to the multi-functional bioactive surfaces of the present invention through the simple additional step **of linking or entrapping biocompatible agents** into the crosslinked polymer network forming the surface coating. Thus, these enhanced biocompatible or bioactive properties can be achieved **without sacrificing the lubricating properties of the unmodified, crosslinked surface coatings**.

This passage is quite clear that the lubricating qualities of the surface are not due to the PVP/PA, but rather to the "unmodified, crosslinked surface coatings." Without that specific coating, the message of Hsu et al. is clear - including a "biocompatible agent" such as PVP/VA would have a

detrimental effect on lubricity. Again, Hsu et al. explicitly identify PVP/PA, by name, as a "biocompatible agent" that is entrained within Hsu's coating. Thus, according to the explicit teaching of Hsu et al., PVP/VA is expected (as clearly indicated by the above-quoted passage) to detrimentally impact the lubricity of Hsu's unmodified, crosslinked surface coatings.

Applicants thus submit that the combination of Ding and Hsu et al. suggested by the Office is improper because Hsu et al. explicitly teaches that including PVP/VA in the coating is likely to decrease its lubricity, not increase it. At no point in the Hsu et al. reference do the authors state that PVP/PA can be used to increase the lubricity of the unmodified coating.

The Kollidon Reference is cited solely for its description of a particular type of PVA/VA copolymer. Note, however, that in the same fashion as Exhibit A attached hereto, the Kollidon Reference points out the extreme hydrophilicity of PVA/VA. See page 7, Section 3.3 of the Kollidon Reference: "Nevertheless, Kollidon VA 64 usually still **absorbs too much water**, so that it can seldom be used as the sole film-forming agent in a formulation."

The Kollidon Reference is also irrelevant in the contact of films for implantable medical devices. The Kollidon Reference is directed entirely to using PVP/VA as a dry-binder or film former for formulating tablets. See section 3 of the reference, starting at page 6.

Thus, combining Ding, Hsu et al., and Kollidon neither teaches nor suggests the claimed invention. Therefore these two rejections are improper and should be withdrawn.

The four-way combination including the Sass reference does not cure the shortcomings of the three-way combination of Ding, Hsu et al., and the Kollidon reference. The Sass patent is cited solely for its teaching of 17β-estradiol. Therefore, Sass is irrelevant to the discussion above with respect to Ding, Hsu et al, and Kollidon. The shortcomings of those three references, as discussed above, remain even when combined with Sass.

Applicants note that 17β-estradiol is recited only in Claim 8 of the present application. Thus, the Sass patent is irrelevant to Claims 1-7 of the application, none of which recite 17β-estradiol.

The only coating described in the Sass patent is diamond-like carbon (DLC). See Sass at column 3, lines 50-58. Therefore the coating described in Sass is unrelated to any of the coatings described by Ding, Hsu et al, and the Kollidon Reference. In short, the underlying coating as recited in present Claim 1 is not taught or suggested by the combination of Ding, Hsu et al, and

the Kollidon Reference. Tossing Sass into the mix does not yield the present invention because there's no motivation to combine Ding, Hsu et al, and the Kollidon reference in the first place, and Sass is only nominally relevant in that it mentions 17β-estradiol.

As noted earlier there is no motivation provided by any of Ding, Hsu et al. or the Kollidon reference to use PVP/VA in Ding's formulation. The combination destroys the utility of the Hsu et al. coating (as noted in Applicants' prior response), so Hsu et al. actually teaches away from the combination. Ding is totally silent with respect to any PVP-containing polymer or copolymer, so it cannot provide any source of motivation for making the combination. The Kollidon reference is directed to coatings for tablets, not implantable medical devices. And the only coating mention by Sass, diamond-like carbon, it totally unrelated to any copolymeric, drug-eluting coating. Thus, the only source of motivation for making the combination is Applicants' own specification. However, the Office cannot use the Applicants' specification to provide the motivation or suggestion to combine that is absent from the applied references.

For these reasons, Applicants submit that the two rejections of the claims under 35 USC §103(a) are improper. Withdrawal of the two rejections is respectfully requested.

Respectfully submitted,

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